DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1, 2, 21, 22 and 31, drawn to rosiglitazone salts.

Group II, Claims 1, 3-5, 21, 2 and 31, drawn to polymorph A.

Group III, Claims 1, 6-8, 21, 22 and 31, drawn to polymorph B.

Group IV, Claims 1, 9-12, 21, 22 and 31, drawn to polymorph B1.

Group V, Claims 1, 12-14, 21, 22 and 31, drawn to polymorph C.

Group VI, Claims 1, 15-17, 21, 22 and 31, drawn to polymorph D.

Group VII, Claims 1, 18-22 and 31, drawn to polymorph E.

Group VIII, Claim 23, drawn to a process.

Group IX, Claims 24 and 25, drawn to a process.

Group X, Claims 26 and 28, drawn to a process.

Group XI, Claim 27, drawn to a process.

Grouo XII, Claims 29 and 30, drawn to a process.

Group XIII, Claim 32, drawn to compositions and uses requiring an additional active ingredient.

Group XIV, Claim 33, drawn to multiple uses.

The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-VII are drawn to independent and distinct forms for which a process of making one form would not make another form, thus the salt forms lack unity of invention. Further, the specification provides evidence that the instant salt and its forms are made by materially different processes.

Groups I-VII and XIV are related as products and multiple uses. In the instant case, the products as claimed can be used in materially different processes as evidenced by applicants' own claims and specification.

Groups I-VII and XIII are unrelated because the compounds of Groups I-VII do not require an additional active ingredient for their use.

The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds claimed contain a pyridine, which does not define a contribution over the prior ar as evidenced by the anticipatory references recited on applicants' international search report. The substituents on the structure vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

In the event of an election of Group XIV, applicants are requested to elect a single compound and single disclosed method, *i.e.,* a specific disease.

In the event of an election of Group XIII, applicants are requested to elect a single disclosed mixture

Because these inventions lack unity of invention for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is *presented prior to* final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be **allowable,** the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant may file the divisional subject matter noted in divisional applications. If applicant wishes a generic expression of the elected invention the claims here need be amended to reflect that election.

This restriction requirement is being written as previous experience has indicated that with Foreign applicants and the inherent time delays, applicants' representative is better able to make an informed, correct, election of the invention applicants would wish to have prosecuted here if applicants are given the opportunity to see the restriction requirement laid out, and given the time to make an informed decision.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Patricia L. Morris/
Primary Examiner, Art Unit 1625

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